Analysis of lead extraction results obtained during Q Statistic evaluations on devices submitted as 'lead free' under NSF/ANSI 61

NSF International

P. Greiner, K. Foster, A. Batog, T. Bills

April 25, 2018

NSF International™

Topics:

- Introduction

- Overview of normal evaluations

- Re-expressing results as ug released

- Limitations due to analytical reporting limits

- Results

Introduction

The purpose of this report is to provide insight into the lead release currently observed during routine product evaluations at NSF. Analysis is provided in both the form of the standard's Q test statistic as well as the raw lead released during each of the 9 pour-off days. The report is not intended to propose any alternate or new criterion.

Data has been collected on 692 products submitted to NSF since 2011 as 'lead free'[1]. Results from only select categories of product have been provided, but represents the majority of products samples submitted.

Samples failing lead content verification testing have been excluded as not to skew the characterization of the extraction performance of 'lead free' product.

[1] – Products with a weighted average lead content of their wetted surfaces of no more than 0.25 percent.

Overview of normal evaluations

- Testing is required in triplicate at a minimum

- Products are exposed to a 19-day protocol

- Samples are taken on 9 of the overnight 16-hr dwell periods

- Lead analysis is performed on all 9 pour-off days yielding a minimum of 27 results (9 x 3 reps minimum).

- Results are combined to 1 finding: Q test statistic

- Requirement:
  - 5 ug/L for most section 9 devices
  - 3 ug/L for supply stops, flexible plumbing connectors, and misc. components.

Overview of normal evaluations

Figure B1 – Exposure sequence for mechanical plumbing device
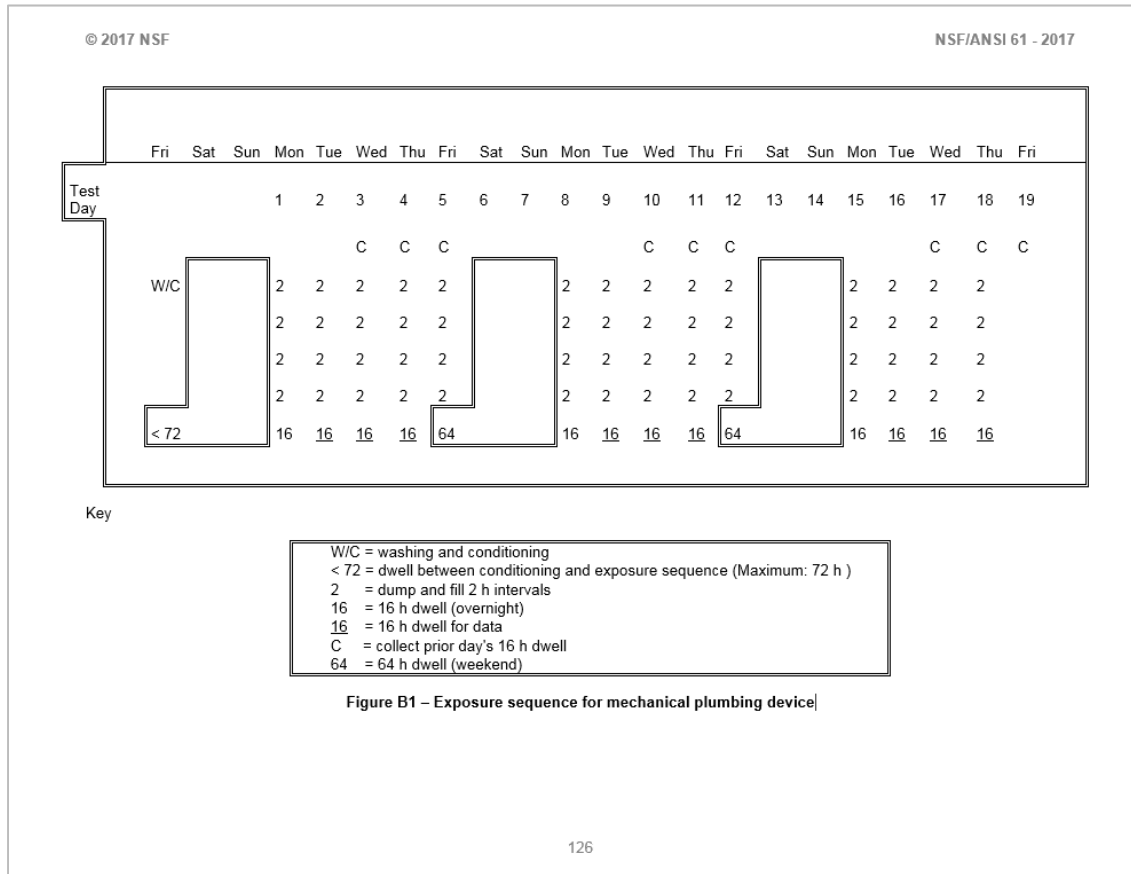
Section 9 exposure protocol

Overview of normal evaluations

Normalization of lab results

$$\text{Normalized Result} = \text{Lab Result} * \frac{SA_F}{SA_L} * \frac{V_L}{V_F} * \frac{\text{Cold Side Volume}}{\text{Total Volume}}$$

B.8.9.2 Calculations

$$D_i = e^{Y_i}$$

and

$$Y_i = \frac{(Y_{i3} + Y_{i4} + Y_{i5} + Y_{i10} + Y_{i11} + Y_{i12} + Y_{i17} + Y_{i18} + Y_{i19})}{9}$$

Calculate the log-dosage mean of Y_i and the log-dosage standard deviation of Y_i for each product, where:

$$\text{Log - dosage mean} = \frac{\sum_{i=1}^{n} Y_i}{n}$$

and

Log-dosage standard deviation =

$$\sqrt{\frac{\sum_{i=1}^{n} (Y_i - \overline{Y})^2}{(n-1)}}$$

B.8.9.3 Initial test statistic

The test statistic Q shall be determined as:

$$Q = e^{\overline{Y}} \cdot e^{k_1 \cdot S}$$

Normalization and Q Statistic

Overview of normal evaluations

Range of Q test statistic values

Description	ND - 1	>1 - 2	>2 - 3	>3 - 4	>4 - 5	>5
Faucets (507)	73.0%	13.4%	6.1%	2.2%	1.4%	3.9%
Flexible Plumbing Connectors (117)	86.3%	9.4%	2.6%	1.7%		
Small Valves (68)	98.5%	1.5%				

Description	ND - 0.5	>0.5 - 1	>1 - 2	>2 - 3	>3
Flexible Plumbing Connectors (117)	71.8%	14.5%	9.4%	2.6%	1.7%
Small Valves (68)	92.6%	5.9%	1.5%		

Re-expressing results as ug released

$$\text{Lead Released During Exposure (ug)} = \text{Lab Result (ug/L)} * \text{Cold Side Volume (L)}$$

Example of faucet with 0.2 L CSV (Q was 7.6 - Failed):

Lab Result (ug/L)

Rep ID	DAY3	DAY4	DAY5	DAY10	DAY11	DAY12	DAY17	DAY18	DAY19
1	27	27	23	20	22	20	18	18	22
2	41	32	29	22	26	21	17	18	17
3	18	16	15	15	15	14	12	13	13

Dose (ug)

Rep ID	DAY3	DAY4	DAY5	DAY10	DAY11	DAY12	DAY17	DAY18	DAY19
1	5.4	5.4	4.6	4	4.4	4	3.6	3.6	4.4
2	8.2	6.4	5.8	4.4	5.2	4.2	3.4	3.6	3.4
3	3.6	3.2	3	3	3	2.8	2.4	2.6	2.6

Average Dose (ug)

	DAY3	DAY4	DAY5	DAY10	DAY11	DAY12	DAY17	DAY18	DAY19
	5.7	5.0	4.5	3.8	4.2	3.7	3.1	3.3	3.5

Concentration versus Dose

When known concentration (ug/L) and volume (L), corresponding dose (ug)

Concentration of lead in water (ug/L)	Volume of Water Consumed (L)	Dosage of lead consumed (L)
15 ug/L	1	15 ug
15 ug/L	0.5	7.5 ug

When known dose (ug), corresponding concentration (ug/L) based on volume (L)

Dosage of lead released from device (ug)	Volume of water dosage released into (L)	Concentration of lead in water (ug/L)
5 ug	1	5 ug/L
5 ug	0.25	20 ug/L
1 ug	1	1 ug/L
1 ug	0.25	4 ug/L
0.5 ug	1	0.5 ug/L
0.5 ug	0.25	2 ug/L
0.25 ug	1	0.25 ug/L
0.25 ug	0.25	1 ug/L

Limitations due to analytical reporting limits

Example of faucet with some non-detectable [1] results (CSV = 0.25 L):

Lab Result (ug/L)

Rep ID	DAY3	DAY4	DAY5	DAY10	DAY11	DAY12	DAY17	DAY18	DAY19
1	2	1	ND(1)	ND(1)	ND(1)	ND(1)	ND(1)	ND(1)	ND(1)
2	1	ND(1)	ND(1)	ND(1)	ND(1)	ND(1)	ND(1)	ND(1)	ND(1)
3	2	2	ND(1)	ND(1)	ND(1)	ND(1)	ND(1)	ND(1)	ND(1)

Dose (ug) – ND results are assumed to be up to the DL

Rep ID	DAY3	DAY4	DAY5	DAY10	DAY11	DAY12	DAY17	DAY18	DAY19
1	0.5	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25
2	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25
3	0.5	0.5	0.25	0.25	0.25	0.25	0.25	0.25	0.25

Average Dose (ug)

	DAY3	DAY4	DAY5	DAY10	DAY11	DAY12	DAY17	DAY18	DAY19
	0.42	0.33	0.25	0.25	0.25	0.25	0.25	0.25	0.25

Analytical reporting limits can restrict ability to report accurate doses on low lead emitting devices.

[1] ND(1): Non-detectable at a reporting limit of 1 ug/L

Limitations due to analytical reporting limits

Potential dose release reporting limits (ug) based on analytical reporting limits (RL)

Cold Side Volume (mL)	If Pb RL = 0.5 ug/L	If Pb RL = 1.0 ug/L
0 - 50	0.025	0.05
> 50 - 500	0.25	0.5
> 500 - 1,000	0.5	1

Concentration versus Dose

When known concentration (ug/L) and volume (L), corresponding dose (ug)

Concentration of lead in water (ug/L)	Volume of Water Consumed (L)	Dosage of lead consumed (L)
15 ug/L	1	15 ug
15 ug/L	0.5	7.5 ug

When known dose (ug), corresponding concentration (ug/L) based on volume (L)

| Dosage of lead released from device (ug)	Volume of water dosage released into (L)	Concentration of lead in water (ug/L)
5 ug	1	5 ug/L
5 ug	0.25	20 ug/L
1 ug	1	1 ug/L
1 ug	0.25	4 ug/L
0.5 ug	1	0.5 ug/L
0.5 ug	0.25	2 ug/L
0.25 ug	1	0.25 ug/L
0.25 ug	0.25	1 ug/L

Analytical reporting limits could limit ability to attest to these lower doses if NDs are evaluated as if the RL.

Evaluation of lead released by day during exposure in ug

Percentage meeting alternate criterion
- Faucets
  (excluding commercial)

Data Summary:
Percentage of jobs passing by pour-off day when average lead dosage level for each test is compared to an alternate criteria of 0.5, 1, 3, and 5 ug release.
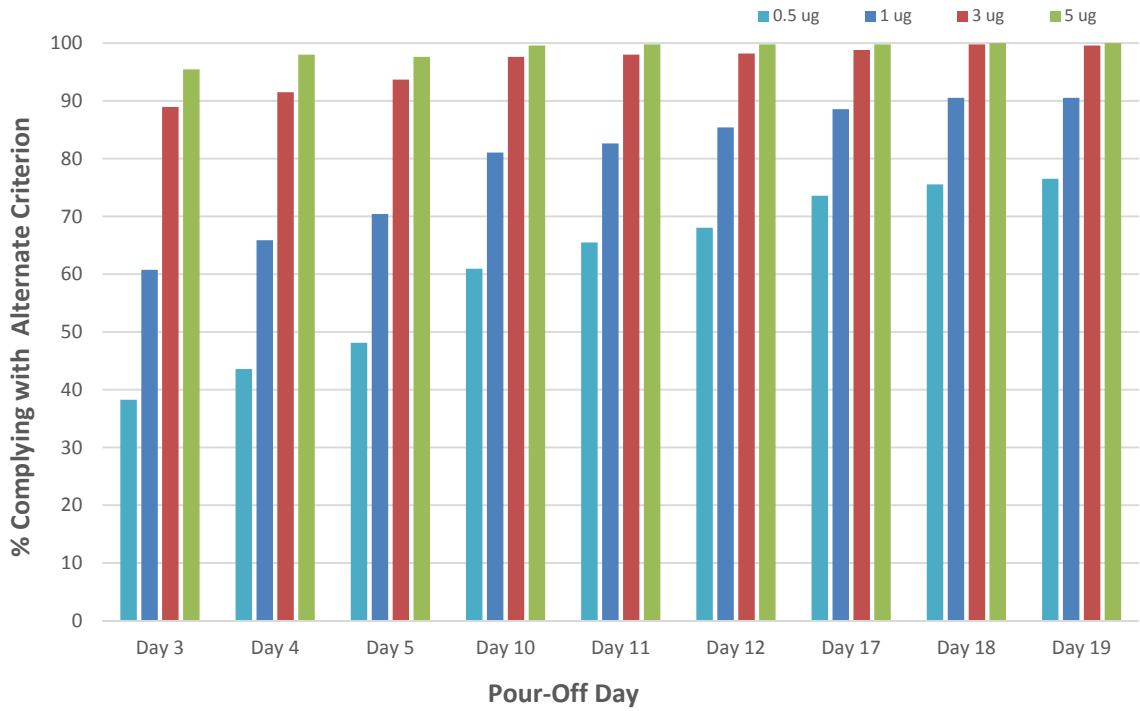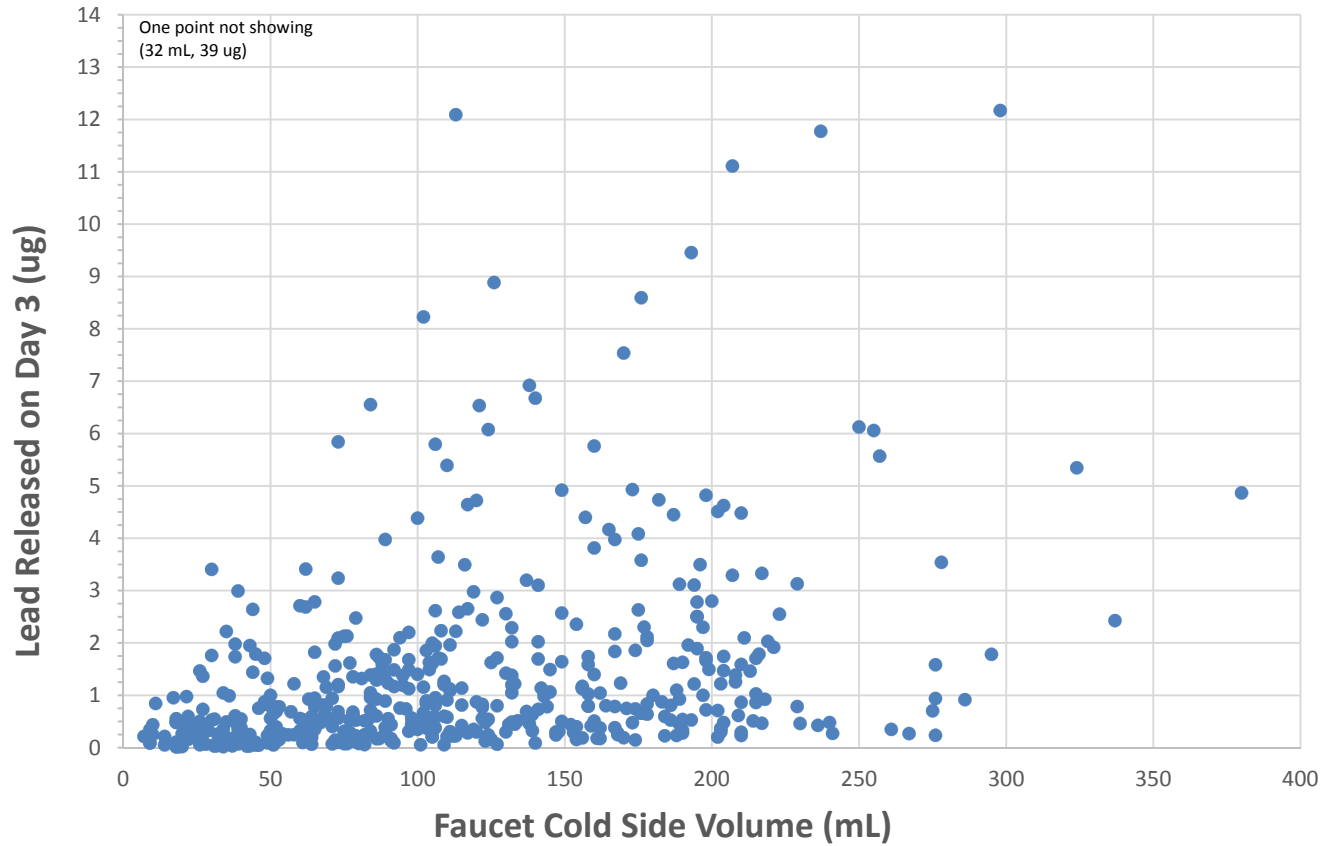

Data for chart (% complying)

Alternate Criterion	Day 3	Day 4	Day 5	Day 10	Day 11	Day 12	Day 17	Day 18	Day 19
0.5 ug	38	44	48	61	65	68	74	75	77
1 ug	61	66	70	81	83	85	89	91	91
3 ug	89	92	94	98	98	98	99	100	100
5 ug	95	98	98	100	100	100	100	100	100

Associated Q Statistics for samples

	ND - 1	>1 - 2	>2 - 3	>3 - 4	>4 - 5	>5	Total
Count	370	68	31	11	7	20	507
%	73.0%	13.4%	6.1%	2.2%	1.4%	3.9%	100%

Average Lead Release on Day 3 into Device

- Faucets (excluding commercial)

One point not showing (32 mL, 39 ug)
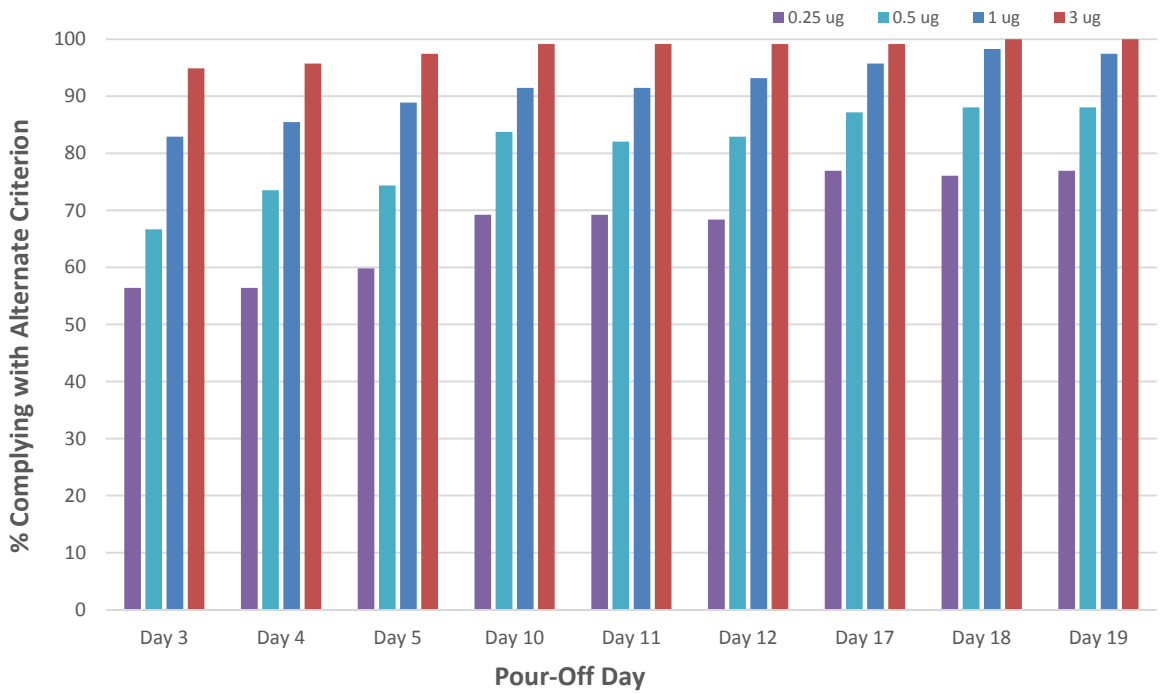
X-axis: Faucet Cold Side Volume (mL)
Y-axis: Lead Released on Day 3 (ug)

Evaluation of lead released by day during exposure in ug

Percentage meeting alternate criterion
- Flexible Plumbing Connectors

Data Summary:
Percentage of jobs passing by pour-off day when average lead dosage level for each test is compared to alternate criteria of 0.25, 0.5, 1, and 3 ug release.
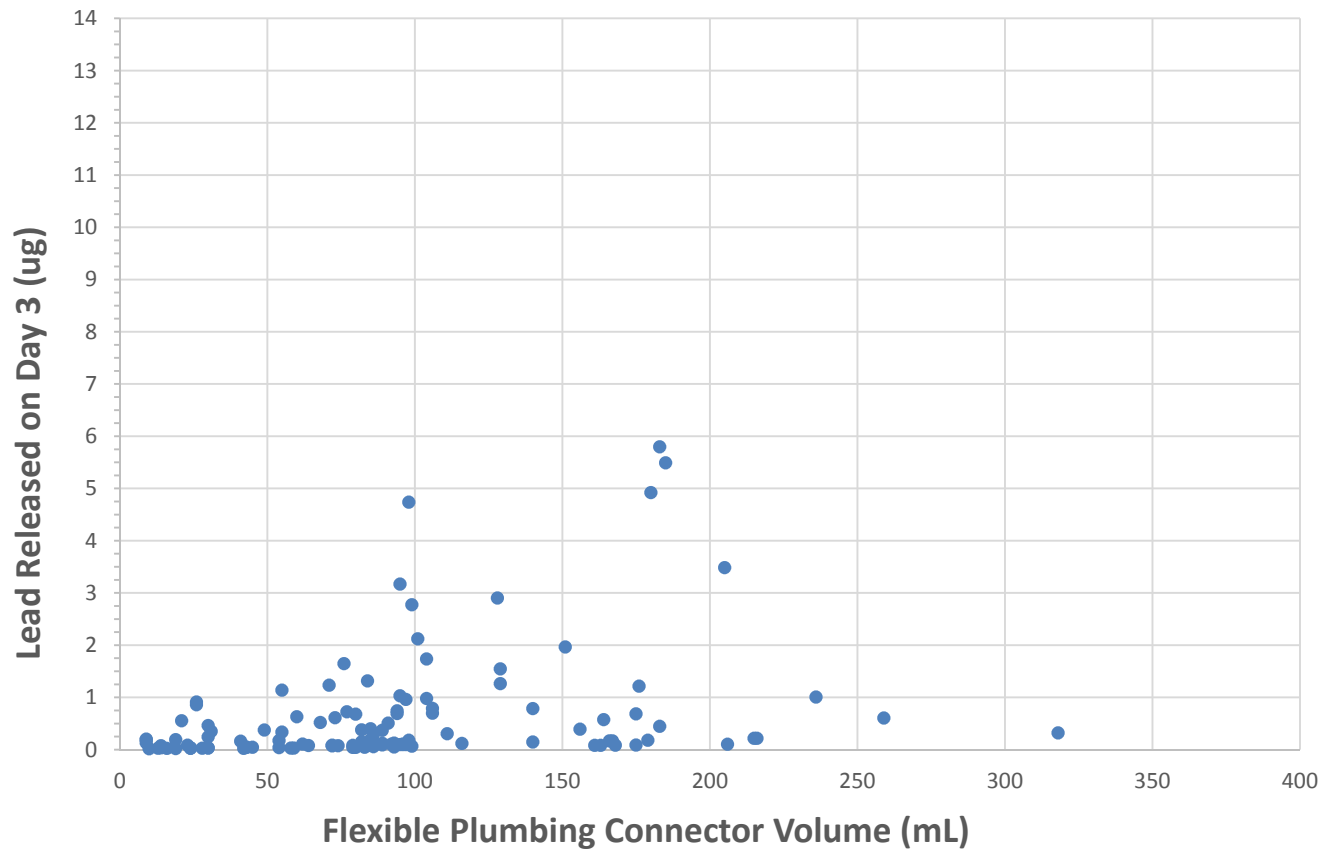

Data for chart (% complying)

Alternate Criterion	Day 3	Day 4	Day 5	Day 10	Day 11	Day 12	Day 17	Day 18	Day 19
0.25 ug	56	56	60	69	69	68	77	76	77
0.5 ug	67	74	74	84	82	83	87	88	88
1 ug	83	85	89	91	91	93	96	98	97
3 ug	95	96	97	99	99	99	99	100	100

Associated Q Statistics for samples

	ND - 0.5	>0.5 - 1	>1 - 2	>2 - 3	>3	Total
Count	84	17	11	3	2	117
%	71.8%	14.5%	9.4%	2.6%	1.7%	100%

Average Lead Dose on Day 3 into Device
- Flexible Plumbing Connectors

Evaluation of lead released by day during exposure in ug

Percentage meeting alternate criterion

- Small Valves

 (supply stops and other small end point valves)

Data Summary:
Percentage of jobs passing by pour-off day when average lead dosage level for each test is compared to alternate criteria of 0.25, 0.5, 1, and 3 ug release.

Legend: ■ 0.25 ug ■ 0.5 ug ■ 1 ug ■ 3 ug
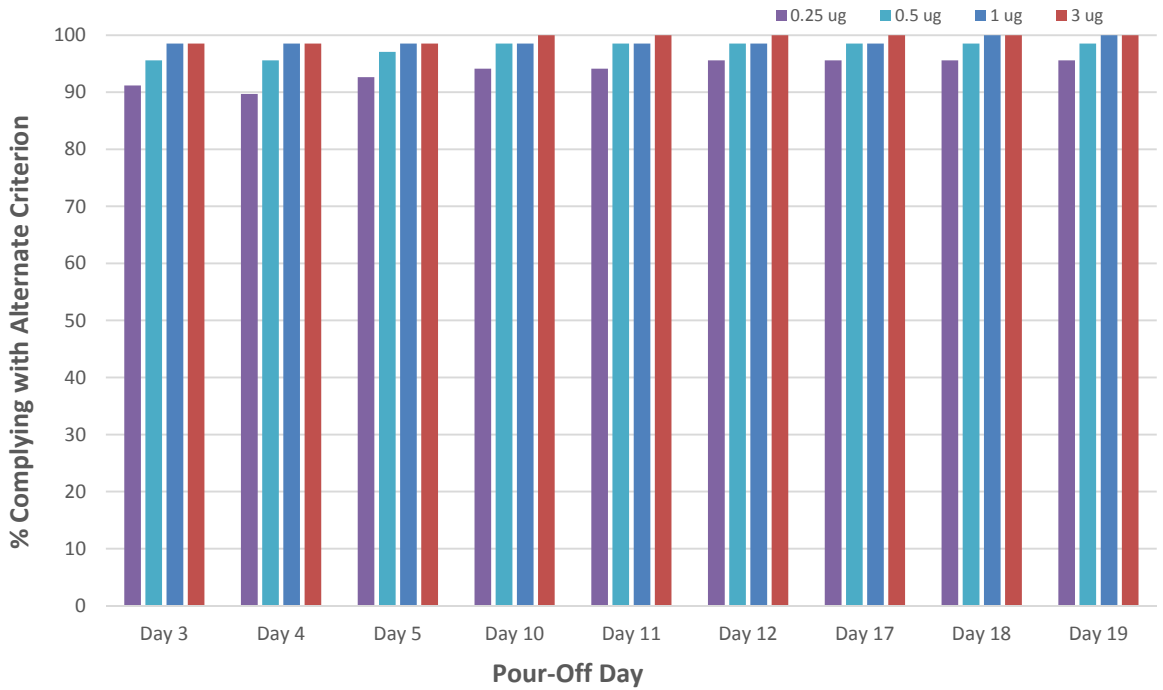
Data for chart (% complying)

Alternate Criterion	Day 3	Day 4	Day 5	Day 10	Day 11	Day 12	Day 17	Day 18	Day 19
0.25 ug	91	90	93	94	94	96	96	96	96
0.5 ug	96	96	97	99	99	99	99	99	99
1 ug	99	99	99	99	99	99	99	100	100
3 ug	99	99	99	100	100	100	100	100	100

Associated Q Statistics for samples

	ND - 0.5	>0.5 - 1	>1 - 2	>2 - 3	>3	Total
Count	63	4	1			68
%	92.6%	5.9%	1.5%			100%

Average Lead Dose on Day 3 into Device

(Volumes includes device and any connected tubing)

- Small Valves
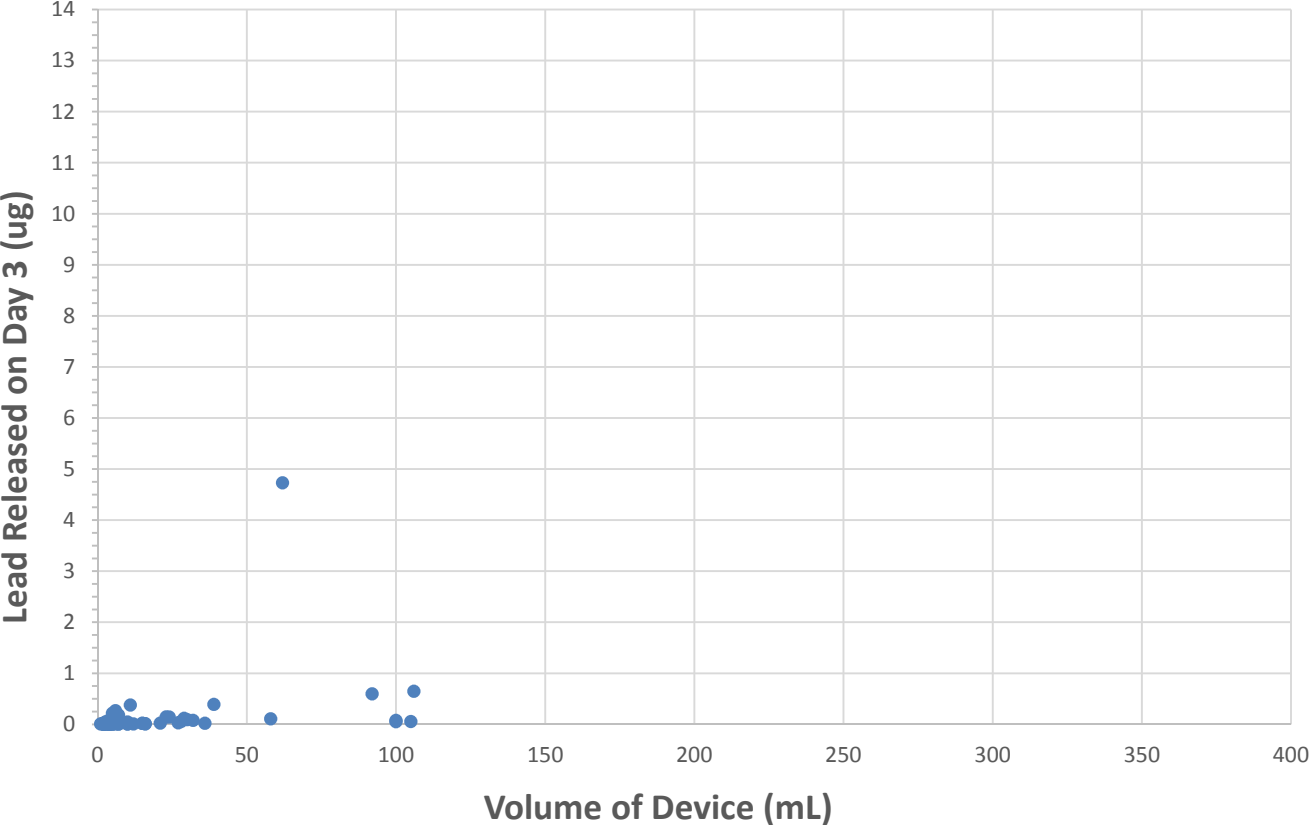
Conclusions:

1. Report is simply intended to provide characterization of lead extraction results on 'lead free' product and to support discussion of current and alternate criterion.

2. Analytical reporting limits can restrict how low the lead release criterion can be set and attested to, especially on higher volume products.

Questions: